**Objectives**

- List the basic considerations of a high performing sterile compounding area
- Define the three key fundamentals of the systems approach to identify opportunities for improvement
- Describe the process of transition from current state to an ideal state
- Propose how to utilize insourcing as a business model to reach a high performing sterile products area

**TMC’s Current State in 2012**

- Highly reliant on outside compounding pharmacies for the production of sterile compounds
- Shift to a majority of compounded sterile preparations (CSPs) are now prepared in-house aka insourcing

**TMC’s Goals for Sterile Compounding**

- Profitability of the Organization
  - Positive ROI
- Operational Performance
  - Efficient Workflows
  - Processes
- Safety/Quality
  - Inventory Management
  - Supply Management

**TMC’s Ideal Future State**

- High performing sterile products area
  - Accountable for all compounding
  - No medication errors
  - Standardization
  - 100% Compliant with regulations
  - Resources
  - Efficient Processes/ No waste
  - State of the Art Facility
  - Automation/ Technology

**Strategic Approach**

- Establishing scope of compounding services
- Systems approach for service redesign
  - Evaluation
  - Implementation
  - Financial impact
Tufts Compounding Services

- Compounding complexity
  - Medium-Risk Level
- Compounded sterile preparation
  - Sterile to sterile compounding
- Beyond Use Dating
  - Does not exceed USP chapter <797>
- Compounding In-House

Basic Considerations

- Framework for enhancing sterile compounding services and redesign
  - Locations serviced/vendor reliance
  - Regulations, quality elements and risk
  - Staff roles and responsibilities
  - Inventory management and supplies
  - Environment and facilities
  - Technology, tools, and resources

System Approach: Model Comparison

<table>
<thead>
<tr>
<th>Model</th>
<th>Strength</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIEPS model</td>
<td>- Focus on design</td>
<td>- Descriptive model; no specific guidance as to</td>
</tr>
<tr>
<td></td>
<td>- Description of systems, its</td>
<td>the critical elements</td>
</tr>
<tr>
<td></td>
<td>component and interactions among components</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Broad view of processes</td>
<td></td>
</tr>
<tr>
<td>Reason/Vincent</td>
<td>- Focus on etiology of accidents and adverse events</td>
<td>- No discussion on processes</td>
</tr>
<tr>
<td></td>
<td>- Description of contributing factors</td>
<td>- No guidance for system redesign</td>
</tr>
<tr>
<td>Donabedian's model</td>
<td>- Description of relationships between structure, processes, and outcomes</td>
<td>- Narrow description of structure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Limited description of process</td>
</tr>
</tbody>
</table>

Sterile Compounding Services Redesign

Feasibility and Impact Analysis

The 3 key fundamentals of the systems approach are?

- Work systems, processes and outcomes
- Plan, do, act
- Define, measure, analyze
- Sort, straighten and standardize
Sterile Products Area Vision

- “To provide comprehensive Sterile Products Area (SPA) pharmacy services for all patient care areas via preparation and standardization of IV admixtures to improve the safety of IV medication delivery."
- Adult patient specific infusions
- Insourcing
- Pediatric CPOE

Assessment of Operations

- Observation
- Data analysis
- Staff interviews

Initial Work Systems: Staff

<table>
<thead>
<tr>
<th>Staff</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>0800-1600</td>
<td>Videos</td>
</tr>
<tr>
<td>0630-1630</td>
<td>Competencies</td>
</tr>
<tr>
<td>1630-2300</td>
<td>“only as good as the teacher”</td>
</tr>
<tr>
<td>3 Technicians</td>
<td></td>
</tr>
<tr>
<td>1 Technician</td>
<td></td>
</tr>
</tbody>
</table>

Initial Work Systems: Technology and Tools

- Recipe
- Handwritten log sheets
- Drug component lot number
- Batch Lot Number (Tech)
- Expiration (Tech)
- Quantity of batch

Initial Work Systems: Regulatory Compliance

- USP 797/795
- JCAHO
- CMS

Initial Work Systems: Locations Serviced/Vendor Reliance

- Heavy Reliance on Outsourced Compounders
  - 45 line items
  - 70,000+ compounded sterile products (CSPs)/month
Initial Work Systems: Facilities/Environment

- ISO 8 Gown Room
- ISO 7 Buffer Room
- ISO 7 Prep Room
- ISO 5 Room
- 2 ISO 5 Hoods (1 BSC)
- Walk-in refrigeration unit
- 4 carousel fridges
- 2 carousels

Initial Processes

**Inventory/Supplies**
- Did not reflect daily needs
- Multiple concentrations/multiple sizes
- No organization

**Tasks**
- None assigned
- “multi-task”

**Quality Assurance**
- RPh outside of Sterile Products Area.
- Verification by empty vials, written adds by tech.
- No oversight
- “normalization of deviance”

Initial Processes: Workflows

- Label
- Calculation to pick right concentration of drug
- Trays/Carts
- All by same tech.
- RPh verifies

Initial Processes: Workflows

- 1 tech
- 2 checking tables
- Finished product stored:
  - Walk in
  - Carousel
  - Prep room

Implementation

- “Toolbox”
  - Case Reports
  - Audit tools (Gap Analysis, BOP)
  - ASHP Best Practices
  - ASHP INSOURCING Sterile Compounding Services Readiness Assessment Tool
  - ISMP: Guidelines for SAFE preparation of Sterile Compounds

Which of the following is not a key element you should consider when enhancing your sterile compounding services?

- Product Integrity and Reliability
- Compliance and Regulations
- Efficient workflows and processes
- Robotics
Present Work Systems: Staff

- **Staff**
  - 0800-2300: 1 RPh
  - 0630-1630: 3 Technicians
  - 1200-2030: "batch tech"
  - 2000-2300: 1 Technician

- **Training**
  - Standard Approach
  - Competencies
    - General
    - Specific
  - "stop the line"

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Present Work Systems: Regulatory Compliance

- USP 797
- JCAHO
- CMS
- Board of Pharmacy

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Present Work Systems: Vendor Reliance

- Decreased to 15 line items
  - Controlled substances
  - Anesthesia syringes
  - Dependent upon manufacturers for vials/bags

---

Present Processes: Inventory and Supplies

- Inventory reflects needs:
  - Par levels
  - Organized!
  - Set up to ease workflow

---

Present Processes: Inventory and Supplies

- Additional Carousel Refrigerator
  - Insourced CSPs
  - Pull method
  - Just in Time production
Present Work Systems: Technology and Tools

- New Labeling system
- Log label
  - Directs tech to appropriate vial or MFW
- Bins
- Area Clearance

Batch
- Master Formulary Worksheet (MFW)
- Extra Cart
- 3rd party website
- Lot number assigned
- BUD assigned
- Component lot numbers
- Quantity of batch

Facilities/Environment

- Addition of:
  - 2 ISO 5 hoods
  - 1 carousel refrigerator
  - Preventative Maintenance
  - HEPA filters
  - Gown Room
  - Line of Demarcation
  - New flooring

Present Processes: Workflows

- Change of Layout
  - Single Piece Flow
  - Pharmacist’s workstations
- Account for:
  - STATs
  - Twice Daily IV Runs
  - Automated Compounder Use
  - Batches
  - 24 hour preparation

Prep Tech
Adult Tech
Pedi Tech
Batch Tech
Pharmacist

Insurance Preparation Workflow:

1. Prep tech retrieves inventory
2. Prep tech prepares product per ISP
3. 3rd party website and prints label
4. Display product with label and MFW worksheet
5. Pharmacist verifies set-up and Area clearance
6. Pharmacist verifies final product

Processes: Quality Assurance

- Dashboard
- Daily/weekly/monthly tasks
- Standardize processes
- Stay within framework of 797 BUDs
- Prechecks
- Shadowing/spot checks
- Standard Operating Procedures
Standard Operating Procedures

- Provide guidance to all personnel on how to perform each task or role.
- Batch
- Label Product
- High Alert
- Pediatrics/Neonates

Outcomes

- Increase patient safety
  - Ready to administer doses
  - Standardized dose preparations
  - ISMP recommendations
- Decrease costs
  - Increase efficiency
  - Decrease waste
  - Cost avoidance
- Drug shortages

Financial Impact

- SHOW ME THE MONEY!

http://giphy.com

Insourcing Business Model

- Factors driving outsourcing vs. insourcing decision
- Previous costs associated with outsourcing
- Infrastructure needed for insourcing
- Tier approach for implementation
- Change in financial projections by insourcing

TMC Insourcing Decision Tree

Insourcing Decision Tree

- Commercially available/Multiple Concentrations
- Standardize or purchase
- BUD per USP
- Medium Low Risk Level
- Storage in Unit ADC Fridge
- Drug Shortage: Consider alternative product

- Tufts COGS < $ Outsource Vendor
- Tufts COGS > $ Outsource Vendor

TMC Financial Implications

- Increased staffing levels as workload and hours of operations expanded
- Installed software to aid in batch production/QA program
- Increased refrigeration storage in ICUs
- Identified safety measures to address vulnerabilities
- Shifted drug expense toward labor expense in FY14
Funding Enhanced Compounding Services

- Reduced risk/reliance on outside compounding services but increased internal risk warrants added infrastructure
  - Additional staff/expansion of hours
  - Storage/refrigeration
  - Software and dedicated resources to maintain QA program and regulatory compliance
  - BCMP/redesign of the Sterile Products Area

Financial Opportunities

Financial Opportunities: ROI

Financial Implications: Telling the Story

- Utilize insourcing as a business model to reach a high performing sterile products area
- Continue to share with stakeholders and update them on financial performance
- Capitalize on the price increase of outside compounders + avoiding cost prohibitive services = decrease annual operating expense ➔
- Equates to a $550,000 ROI to fund infrastructure
Which of the following components must be considered as part of your business plan when considering insourcing?

- Previous costs associated with outsourcing.
- Infrastructure needed for insourcing.
- Change in financial projections by insourcing.
- All of the above.

Key Takeaways

- **Key Takeaway #1**
  - Consider utilizing a systems approach to enhance and redesign sterile compounding services
  - The SIEPS model of work system and patient safety provides a framework for understanding structure, processes, and outcomes

- **Key Takeaway #2**
  - High impact and high feasibility initiatives can expedite the process of transition from current state to an ideal state

- **Key Takeaway #3**
  - Understanding the financial implications of insourcing may allow you to fund infrastructure needs